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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,312	09/01/2004	Kathleen Ann Taylor	GOW1020US0890578USX15664	8333

65159 7590 03/18/2009

BIO TECHNOLOGY LAW GROUP
C/O PORTFOLIOIP
P.O. BOX 52050
MINNEAPOLIS, MN 55402

EXAMINER	
ZEMAN, ROBERT A	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
03/18/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/506,312	TAYLOR ET AL.	
	Examiner	Art Unit	
	ROBERT A. ZEMAN	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,9,10,12,15,16,18,19,22-28 and 31-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1,3,4,9,10,31-33 and 41* is/are allowed.

6)☒ Claim(s) *12,15,16,18,19,22-28, 34-40 and 42-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 6-26-2007 has been entered.

The amendment filed on 12-24-2008 is acknowledged. Claims 1, 3, 9, 12, 15, 18-19, 26, and 28 have been amended. Claims 2, 5-8, 11, 13-14, 17, 20-21 and 29-30 have been canceled. Claims 34-44 have been added. Claims 1, 3-4, 9-10, 12, 15-16, 18-19, 22-28 and 31-44 are pending and currently under examination.

Claim Objections

Claims 18 and 19 are objected to under 37 CFR 1.75 as being substantial duplicates of claim12. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Said claims are all drawn to methods of increasing IL10 expression in a mammal said methods consisting of the same active step (the administration of the composition of claim 31).

Claims 27 and 28 are objected to under 37 CFR 1.75 as being substantial duplicates of claim 26. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Said claims are all drawn to methods treating or preventing an abscess, sepsis or post-surgical adhesions in a mammal said methods consisting of the same active step (the administration of the composition of claim 31).

Claims 39 and 40 are objected to under 37 CFR 1.75 as being substantial duplicates of claim 34. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Said claims are all drawn to methods the immunological activity of the recited composition in a mammal said methods consisting of the same active step (the administration of the composition of claim 31).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12, 15-16, 18-19, 22-25, 34-40 and 42-44 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of inhibiting the maturation of dendritic cells *in vitro* by contacting said cells with the composition of claim 31;

methods of increasing the expression of IL10 in a mammal by the administration of immature dendritic cells (iDC) that have been pulsed *ex vivo* with the composition of claim 31; methods of preventing abscesses in mammals comprising the administration of the composition of claim 31; methods of measuring the immunological activity of the composition of claim 31 by measuring delayed type hypersensitivity responses to candin; and the prevention of severe post-surgical adhesions in mammals comprising the administration of the composition of claim 31 , does not reasonably provide enablement for methods of increasing IL10 expression in a mammal by the administration of either the composition of claim 31 or the administration of regulatory T cells that have been stimulated by iDCs that have been primed *ex vivo* with the composition of claim 31; the methods of treating any malady comprising the administration of the composition of claim 31 or any cells that have been *ex vivo* primed with said composition; any method of treating or preventing all types of post-surgical adhesions; or any method of treating or preventing sepsis in a mammal. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use invention commensurate in scope with these claims.

Enablement is considered in view of the Wands factors (MPEP 2164.01(A)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, state of the art, predictability of the art and the amount of experimentation necessary.

In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) states, "The amount of guidance or direction needed to enable the invention is inversely related to the amount of

knowledge in the state of the art as well as the predictability in the art." "The "amount of guidance or direction" refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly stated in the specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling" (MPEP 2164.03). The MPEP further states that physiological activity can be considered inherently unpredictable. Thus, Applicant assumes a certain burden in establishing that inventions involving physiological activity are enabled. All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the invention: The instant claims are drawn to methods of increasing IL10 expression in mammals by the administration of the composition of claim 31 (claims 12 and 18-19) or the administration of regulatory T cells that have been contacted with iDCs that have been *ex vivo* primed with the composition of claim 31 (claims 15-16 and 22-25); methods of treating or preventing abscesses, post surgical adhesions or sepsis by the administration of the composition of claim 31 (claims 34, 39-40 and 42-44), the administration of iDCs that were *ex vivo* primed with the composition of claim 31 (claims 35-36) or the administration of regulatory T cells that have been contacted with iDCs that have been *ex vivo* primed with the composition of claim 31 (claims 37-38).

Breadth of the claims:

Claims 34-40 and 42-44 are extremely broad as they encompass sepsis of any etiology and any type of post-surgical adhesion.

Guidance of the specification/The existence of working examples:

To use the invention as claimed one must be able to modify the immune responses in an animal by the administration of the composition of claim 31, iDCs that were *ex vivo* primed with the composition of claim 31 or regulatory T cells that have been contacted with iDCs that have been *ex vivo* primed with the composition of claim 31. While the specification provides great detail on the ability to inhibit dendritic cell maturation and stimulate IL10 and IL19 expression with the claimed composition *in vitro,* the specification is silent with regard to the efficacy of any treatment regimen for abscesses, post-surgical adhesions or sepses or the efficacy of using *ex vivo* primed iDCs or regulator T cells to increasing IL10 expression.

State of the art:

At the time of applicants' invention the synthetic polymeric antigen was not known in the art.

Predictability of the art and the amount of experimentation necessary:

People of skill in the art require evidence that a benefit can be derived by the therapeutic application of a given substance; however, a survey of the relevant art does not indicate that substances such as those claimed provide such benefit. The instant specification fails to provide significant direction on which modalities, if any, are capable of eliciting a therapeutic/protective response when administered to an immunocompetent subject in need. Moreover, the

specification is equally silent on how said compositions are to be administered to said subject. The specification lacks either direct evidence for *in vivo* benefit, or a reasonable basis for correlating the *in vitro* as exemplified in the instant specification with *in vivo* benefit. Hence, the specification cannot be said to teach how to use the claimed composition in the recited methodologies without undue experimentation. Moreover, while those of skill in the art recognize that *in vitro* assays and or cell-cultured based assays are somewhat useful to observe basic physiological and cellular phenomenon such as screening the effects of potential drugs, clinical correlations are generally lacking. The greatly increased complexity of the *in vivo* environment as compared to the very narrowly defined and controlled conditions of an *in vitro* assay does not permit a single extrapolation of *in vitro* assays to *in vivo* efficacy with any reasonable degree of predictability. *In vitro* assays cannot easily assess cell-cell interactions that may be important in a particular pathological state. Furthermore it is well known in the art that cultured cells, over a period time, lose phenotypic characteristics associated with their normal counterpart cell type. Freshney (Culture of Animal Cells, A Manual of Basic Technique, Alan R. Liss, Inc., 1983, New York) teach that it is recognized in the art that there are many differences between cultured cells and their counterparts *in vivo*. These differences stem from the dissociation of cells from a three-dimensional geometry and their propagation on a two-dimensional substrate. Specific cell interactions characteristic of histology of the tissue are lost. The culture environment lacks the input of the nervous and endocrine systems involved in homeostatic regulation *in vivo*. Without this control, cellular metabolism may be more constant *in vitro* but may not be truly representative of the tissue from which the cells were derived. This has often led to tissue culture being regarded in a rather skeptical light (p. 4, see Major

Differences *In Vitro).* Moreover, Dermer (Bio/Technology, 1994, Vol. 12 page 320 - IDS filed on 6-22-2007) teaches that evidence of the contradictions between life on the bottom of a lab dish and in the body has been in the scientific literature 'for more than 30 years. Clearly it is well known in the art that cells in culture exhibit characteristics different from those *in vivo* and cannot duplicate the complex conditions of the *in vivo* environment involved in host-tumor and cell-cell interactions.

Moreover, rejected claims 34-40 and 42-44 are drawn to the prophylactic use of the recited synthetic polymeric antigen. To be a prophylactic composition, the composition must elicit protective immunity, demonstrable by pathogen challenge experiments in a reasonable model system. The specification, as filed, does not set forth that the claimed use of the claimed deletion provides any sort of protective immune response in any model system that can be extrapolated to humans or other mammals. While the skill in the art of immunology is high, to date, prediction of protective immunity for any given composition in any given animal is quite unpredictable.

Consequently, the specification does not enable any person of skill in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 26 contains the trademark/trade name Candin. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a yeast antigen composition and, accordingly, the identification/description is indefinite.

Conclusion

Claims 1, 3-4, 9-10, 31-33 and 41 are allowed.

Claims 12, 15-16, 18-19, 22-28, 34-40 and 42-44 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT A. ZEMAN whose telephone number is (571)272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on (571) 272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert A. Zeman/
Primary Examiner, Art Unit 1645
March 10, 2009